

Artificial intelligence in pathology: from image analysis to clinical decision support

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Abstract

Artificial intelligence is transforming pathology by enhancing diagnostic precision and supporting clinical decision-making. Its application often involves digital imaging and machine learning to analyse whole slide imaging (WSI) data. AI algorithms can detect cellular abnormalities, classify cancers, and predict outcomes more accurately than traditional approaches, enabling faster and more reliable diagnoses. This is especially valuable in cancer pathology, where early detection and precise classification are critical for effective treatment. Despite its benefits, AI faces challenges, including limited data availability, algorithm validation, and seamless integration into clinical workflows. This paper reviews current literature on AI's role in pathology, highlighting its capacity to improve diagnostic accuracy and efficiency while examining barriers to broader adoption. As technology advances, AI holds substantial promise to revolutionize the discipline, ultimately enhancing patient care and reducing diagnostic errors. By addressing challenges, AI-driven pathology may soon become a cornerstone of modern healthcare.

Introduction

Background

Numerous medical decisions directly impact patient health and lives, yet the limited number of specialists and time constraints can compromise care quality. The purpose of using artificial intelligence (AI) in medicine is to integrate the expertise of diverse clinicians and the results of many patient studies to support real-time decision-making. For instance, a well-designed system could recommend alternative treatments for a patient with poorly controlled hypertension [1, 2]. AI also plays a growing role in pathology [3]. Traditionally, tissue samples are preserved, embedded in paraffin, sectioned, stained, and examined under a microscope [4]. In digital pathology, these glass slides are replaced by digitized microscopic images, which can be displayed on a screen, stored on servers or in cloud systems, and shared via the internet [3]. Whole slide imaging (WSI) scans undergo digital processing, enabling AI algorithms to analyse them [4]. The principle of machine learning (ML) involves collecting data – including WSI labelled by pathologists – and creating models that recognize new images based on these observations [2]. WSI applications range from diagnostics and specialist consultations to intraoperative assess-

ments and education [3]. In pathology, where results guide treatment and prognosis, AI-assisted analysis of millions of cells can reduce physicians' workload, shorten result turnaround times, improve cancer diagnosis and classification, and aid in identifying biomarkers or genetic changes [1, 5]. Despite these advantages, AI is expected to serve mainly as a supplemental tool due to its limitations, unpredictable performance with unfamiliar data, and occasional failures [2]. Other barriers include validating and interpreting computational systems and ensuring appropriate engagement by pathologists, clinicians, patients, and regulators [5].

Objectives

The primary aim of this paper is to review existing literature on the use of artificial intelligence in pathology, examine the potential benefits and challenges associated with emerging AI-based technologies, and raise awareness of this evolving field.

Milestones of digital pathology and basic definitions

- 1956 – John McCarthy introduced the term artificial intelligence (AI) as “the science and engineering of making intelligent machines” [5–7].

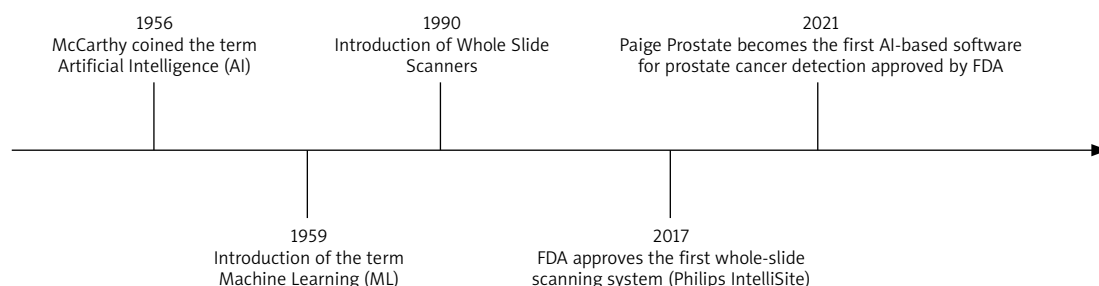


Figure 1. Milestones of digital pathology

- 1959 – Arthur Samuel coined the term machine learning (ML) as “the ability to learn without being explicitly programmed” [3, 6].
- 1965 – Judith Prewitt and Mortimer Mendelsohn conducted a computer analysis of microscopic images of cells and chromosomes from a blood smear, marking the beginning of digital pathology [5, 6].
- 1986 – Rina Dechter introduced the term deep learning (DL) [3, 6, 8].
- 1988 – Yann LeCun invented the convolutional neural network (CNN) [6].
- 1990 – Whole slide scanners were introduced [6].
- 1998 – Tripath became the first company to receive FDA (Food and Drug Administration) approval for the automatic evaluation of cervical smears in screening tests [6, 9].
- 2017 – Philips received FDA approval for the first whole-slide scanning system, Philips IntelliSite [5, 6, 10].
- 2021 – Paige Prostate became the first AI-based software for prostate cancer detection to receive FDA approval [11] (Figure 1).

What is AI?

Artificial intelligence (AI) is a computer-based system intended to emulate human intelligence. It is built using machine learning (ML) techniques, which involve algorithms that learn from datasets, detect patterns, and draw inferences [4, 12]. Deep learning (DL) is a subset of ML that demands larger datasets and longer training times. It relies on intricate neural networks, comprising an input layer, an output layer, and multiple hidden layers [3–12]. Within this framework, artificial neural networks (ANNs) act as statistical models inspired by human neural pathways; through data processing and the dynamic adjustment of “synaptic” connections, these systems can learn, make decisions, and solve problems [3, 12]. Convolutional neural networks (CNNs), another type of DL algorithm, are especially prevalent in image analysis [3, 6]. Creating a DL model typically begins with defining the problem. Data are then gathered and processed – often by digitizing histopathological slides via whole slide imaging (WSI) scanners. Subsequently, the neural network is trained by examining portions of each

image, extracting and ranking relevant features. If the training phase succeeds, the model undergoes rigorous validation in clinical settings. Before any AI tool can be used in practice, however, it must obtain certification from Conformité Européenne (CE) or the U.S. Food and Drug Administration (FDA). Using the resulting data, researchers can develop diagnostic, differential, and prognostic models [2, 11]. In many cases, these models require extensive datasets of digital slides, and when data are insufficient, transfer learning may be employed to leverage knowledge from preexisting models while maintaining high accuracy [2]. One example of a comprehensive resource for such data is The Cancer Genome Atlas (TCGA), which houses high-quality annotated images [5]. Originally, the term “digital pathology” (DP) referred solely to scanning complete histopathological slides at microscopic resolution using advanced scanners. Today, DP also covers AI-based techniques for analysing these digitized images, which can be transmitted through internet-based, remotely controlled microscopy systems for consultation or research purposes [3, 12]. By integrating AI and DP, pathologists can streamline diagnostic processes, collaborate more efficiently, and potentially uncover novel insights into disease processes.

Application of artificial intelligence in pathology

Lung cancer

Lung cancer ranks among the most frequently diagnosed malignancies and represents the leading cause of cancer-related mortality in men, as well as in women over the age of 50 [13]. Despite ongoing efforts, early detection remains challenging, with only about 20% of cases identified at Stage I. Clinicians also face difficulties in accurately assessing prognosis. Consequently, there is a clear need to develop AI-based methods that can enhance diagnostic accuracy and streamline the application of appropriate therapies. Gandhi *et al.* conducted a literature review on PubMed to evaluate AI approaches used in lung cancer diagnosis and management. Table 1 summarizes the relevant studies detailing AI applications in lung cancer pathology [14].

Table 1. Summary of studies on the use of AI in lung cancer diagnosis [14]

Variable	Flores-Fernandez <i>et al.</i> , 2012	Yu <i>et al.</i> , 2016	Teramoto <i>et al.</i> , 2017	Coudray <i>et al.</i> , 2018
Data set	Serum biomarkers from 63 lung cancer patients	2480 histopathological images of lung adenocarcinoma	298 histopathological images	Pathological images of adenocarcinoma
AI algorithm	ANN	SVM Random forest	Conventional deep neural networks	Conventional deep neural networks
Application	Biomarker-based classification of lung cancer patients	Differentiation between healthy and malignant tissue	Classification of cancer into adenocarcinoma, squamous cell carcinoma, and small cell carcinoma	Searching for the 10 most common genes in adenocarcinoma
Results	Correct classification rate = 93.3%	AUC = 0.81	Accuracy = 89%, 60%, 70% respectively	Accuracy = 73.3–85.6%

SVM – support vector machine, ANN – artificial neural network.

The quality of their labelling was evaluated through the area under the curve (AUC) of the receiver operating characteristic (ROC), a metric for gauging classification accuracy. Typically, an AUC ranging from 0.7 to 0.8 indicates acceptable accuracy, 0.8 to 0.9 signifies excellent performance, and anything above 0.9 is considered outstanding. Notably, the described system achieved an AUC of 0.97, illustrating an outstanding classification performance [4]. Another study by Yang *et al.* involved a classifier that differentiated 1,067 microscopic slides into lung cancer, tuberculosis, pneumonia, or normal tissue subtypes [15]. When tested with slides from four different medical centres, the algorithm's AUC values ranged between 0.918 and 0.978, indicating high reliability and robustness across multiple datasets [15]. Meanwhile, Shim *et al.* used over 1,000 slides to train a deep learning model called DeepRePath for predicting patient outcomes following early-stage lung adenocarcinoma resection [16]. The model produced AUC values of 0.77 and 0.76 in cohorts 1 and 2, respectively, signifying moderate predictive capacity. Although it effectively identified high-risk patients for recurrence, its relatively low efficiency prevented it from being used as a fully automated clinical tool [16]. Beyond classification and prognostic modelling, AI techniques are increasingly employed to discover novel biomarkers for disease. One such biomarker is tumour-infiltrating lymphocytes (TIL), essential in mounting an antitumor immune response [17]. Measuring TIL levels in the tumour microenvironment can assist in both the diagnosis and recurrence prediction of non-small-cell lung cancer (NSCLC). However, manual TIL assessment presents significant challenges, making AI-based solutions an attractive alternative [17]. For instance, Park *et al.* introduced an AI-driven TIL analyzer (Lunit SCOPE 10) that groups TIL into three immune phenotypes to predict therapeutic response in patients with advanced NSCLC, producing encouraging preliminary results [18]. Moreover, tumour

response to immunotherapy often correlates with the expression of programmed cell death protein 1 (PD-1), its ligand (PD-L1), and the tumour mutation burden (TMB) [19]. Generally, a favourable response is linked to high PD-L1 expression and elevated TMB. Rakaee *et al.* examined a machine learning algorithm that assesses TMB and PD-L1 levels, revealing that combining TIL with PD-L1 or TMB with PD-L1 leads to improved prognostic predictions compared to evaluating PD-L1 alone [20]. These findings raise optimism for more precise and effective treatments for patients with NSCLC.

Assessment of cancer stage and prognosis

AI significantly impacts cancer diagnosis, treatment, and recurrence prediction [4, 21, 22]. It automatically analyses medical images (CT, MRI, mammography) to detect and stage tumours, supporting TNM classification [4, 22]. AI also helps determine surgical margins, assess recurrence risk, and personalize therapy based on genetic data, while forecasting survival and treatment response for early recurrence detection [23]. A prominent example is the CAMELY-ON16 challenge, where AI and pathologists examined sentinel lymph nodes in breast cancer [24]. Detecting node metastases is pivotal for therapy planning [5, 22]. AI analysed histopathological slides with accuracy matching or surpassing experienced pathologists, especially for microscopic metastases [5, 24]. Research confirmed AI's superior performance in breast cancer metastasis detection; pathologists achieved AUC 0.994 [25, 26], while the Lymph Node Assistant (LYNA) reached 0.996 [6, 25], correctly identifying two previously misdiagnosed cases. Vandenberghe *et al.* reported LYNA boosted micrometastasis sensitivity from 83% to 91% [23], significantly reducing pathologist review time [5, 27]. By automating workflows, AI mitigates overlooked micrometastases, improving treatment outcomes and enabling earlier interventions [5,

23]. Early detection of pathological changes improves survival. Circulating tumour cells (CTCs) are critical for early monitoring; elevated counts indicate aggressive disease. Minimally invasive blood draws facilitate CTC analysis. Zeune *et al.* showed a deep learning algorithm yielded more accurate CTC counts in prostate and non-small cell lung cancer than manual methods [28].

Breast cancer

Artificial intelligence (AI) is increasingly integral to breast cancer pathology, aiding in tissue sample analysis and improving diagnostic accuracy. Breast cancer is the most common malignancy in women [29]. A core pathology task is to distinguish tumours from normal tissues and benign from malignant lesions, which informs treatment strategies. Araújo *et al.* achieved 83.3% accuracy in classifying whole slide images (WSIs) as cancerous versus non-cancerous, and 77.8% accuracy for four-class categorization [30]. Similarly, Wang *et al.* reported that combining pathologists' expertise with AI reduced human error by 85% and raised the AUC from 0.966 to 0.995 when detecting breast cancer metastases in sentinel lymph nodes [31]. These advances underscore AI's potential to refine diagnostics and personalize therapy [32]. AI-powered algorithms can rapidly analyse microscopic tissue images, identifying subtle cellular abnormalities and differentiating *in situ* from invasive tumours. They also automate crucial measures like the mitotic index, indicating tumour aggressiveness [33, 34]. Beyond morphological analysis, AI can detect and quantify key biomarkers (e.g., oestrogen, progesterone, and HER2 receptors), enabling targeted therapies [33–35]. By standardizing evaluations that can vary among pathologists, AI reduces subjectivity and enhances reliability [33, 34]. It also detects precancerous changes like atypical hyperplasia, potentially preventing invasive disease [33, 34]. Finally, AI-driven predictive models leverage large patient datasets to forecast disease progression and survival, aiding oncologists in treatment planning and follow-up [35, 36].

Ovarian cancer

Ovarian cancer is frequently diagnosed at later stages, resulting in less effective treatment and a more guarded prognosis [37, 38]. To address this challenge, AI-based approaches assist pathologists by rapidly analysing tissue images to detect cancer cells, thereby expediting the diagnostic process. Through advanced algorithms, AI can also differentiate between various ovarian cancer subtypes – such as serous, endometrial, and mucinous – enabling precise tumour identification and optimal therapy selection [37]. A key advantage of AI lies in its capacity for tissue segmentation and pattern extraction. Automatic segmentation enables the identification of regions containing

cancer cells, an essential step in disease staging. By examining morphological characteristics – such as cell size, shape, nuclear arrangement, and other structural attributes – AI provides valuable prognostic insights into the tumour [37]. Additionally, AI supports immunohistochemical biomarker analysis, which is crucial for determining targeted therapy strategies. By accurately assessing the expression of markers such as p53 and Ki-67, AI not only streamlines this evaluation but also enhances its precision, informing potential responses to specific treatment modalities [38]. Another benefit of AI in pathology is its ability to minimize diagnostic errors that could lead to sub-optimal treatment. Machine learning algorithms can detect subtle distinctions between healthy and malignant tissues, thereby reducing false-positive and false-negative diagnoses [38, 39]. Acting as a “second opinion”, AI reinforces pathologists' conclusions and diminishes the likelihood of mistakes. Additionally, AI excels at analysing high-resolution tissue images, illuminating the tumour microenvironment and pinpointing minor tissue alterations that may be imperceptible to the human eye [37, 38]. By examining extensive histopathological datasets, AI can uncover distinctive patterns, broadening our understanding of ovarian cancer biology and supporting the development of innovative therapeutic strategies [37, 38]. Finally, AI proves especially valuable for identifying ovarian cancer metastases, which are pivotal for selecting and guiding treatment [39, 40]. Algorithms can detect metastases at earlier stages, ensuring more rapid intervention, and AI-enabled systems can also track disease progression – essential for monitoring patients following therapy. Together, these capabilities underscore AI's potential to significantly improve the accuracy, efficiency, and efficacy of ovarian cancer diagnosis and management.

Uterine cancer

Artificial intelligence (AI) is transforming the field of uterine cancer pathology by improving how this disease is diagnosed, classified, and treated. Uterine cancer – particularly endometrial cancer, which affects the uterine lining – is one of the most common gynaecological malignancies, making early and accurate diagnosis essential for effective therapy. AI can greatly facilitate this diagnostic process through deep learning algorithms that automatically examine tissue samples from the endometrium, detecting malignant cells more rapidly and precisely. Moreover, AI can distinguish between different histological subtypes of endometrial cancer – such as endometrioid, serous, or clear cell tumours – a critical step in determining the most appropriate treatment plan [41]. Biomarker evaluation is another area where AI offers significant advantages in uterine cancer pathology. By analysing immunohistochemical staining, AI algorithms help

determine the presence of key hormonal receptors (oestrogen and progesterone), which can guide treatment choices in hormone-sensitive cancers. AI can also assess proteins such as p53 and HER2, aiding in the classification of endometrial cancer and predicting responses to specific therapies [41, 42]. Given the importance of accurately assessing tumour malignancy, AI's ability to analyse cell morphology, mitotic rates, and growth patterns proves invaluable. This information helps refine tumour grading and supports more precise staging, ensuring that patients receive the most suitable treatment [41–43]. AI can further detect precancerous changes, such as endometrial hyperplasia, which may evolve into uterine cancer. Algorithms are capable of differentiating between simple and atypical hyperplasia, an essential distinction for gauging the likelihood of cancerous transformation. Early recognition of these precancerous states enables closer monitoring and proactive interventions before full-blown malignancies develop [42]. Additionally, AI-driven approaches can customize treatment for individual patients by drawing on data derived from similar cases. By examining both treatment histories and cell morphology, AI can predict therapeutic responses – whether to hormone therapy, chemotherapy, or radiotherapy – and estimate the risk of recurrence, thereby paving the way for more personalized treatment plans [41–43].

Prostate cancer

Prostate cancer diagnostics has emerged as one of the most dynamic areas for the application of deep learning, largely due to the close relationship between cancer malignancy and tissue morphology [4, 43]. AI has shown promise in enhancing diagnostic accuracy, assessing malignancy, and aiding treatment planning. As it is one of the most prevalent cancers in men, early detection and precise evaluation of prostate cancer are crucial for effective treatment. By automating tissue biopsy image analysis, AI can more rapidly and accurately detect cancer cells, distinguishing them from healthy tissue – a fundamental task for confirming the presence of prostate cancer. Moreover, AI can classify various cancer subtypes and identify patterns not easily discernible by the human eye [44]. Malignancy assessment in prostate cancer relies on the Gleason scale, a key tool for making therapeutic decisions. AI algorithms can accurately gauge the architectural patterns of cancer cells and assign appropriate Gleason scores, helping to standardize results and reduce interpretive variability among pathologists – factors crucial to reliable malignancy assessment. Beyond this, AI can precisely segment and evaluate the tumour microenvironment, identifying distinct tissue components (e.g., glands, stroma, blood vessels) to locate cancerous regions with greater accuracy [45–47]. By examining how cancer cells interact

with their surrounding tissue, AI also provides additional insights into potential aggressiveness. In 2020, Bulten *et al.* employed machine learning to analyse prostate biopsy samples and achieved notable success. Trained on 5,759 images, their system demonstrated high diagnostic accuracy, effectively differentiating benign from malignant lesions (AUC 0.99). It was also capable of classifying Gleason patterns with results comparable to those of human pathologists [48]. AI further supports biomarker evaluation, which is critical for predicting disease progression and personalizing treatment. Through AI-enhanced immunohistochemical analysis, pathologists can assess levels of biomarkers such as PSA (prostate-specific antigen), AMACR (alpha-methylacyl-CoA racemase), and p53 – factors that can guide decisions about hormone therapy, radiation, or other treatment modalities [45]. AI algorithms can also forecast the likelihood of prostate cancer progression, aiding physicians in patient monitoring and long-term management. By examining large datasets, AI can estimate the risk of disease advancement on the basis of histopathological features and clinical parameters. These predictions regarding potential recurrence can help clinicians schedule follow-up tests more effectively and tailor therapeutic approaches [45, 46].

Liver diseases

Diagnosing liver fibrosis is challenging due to subtle contrast differences between healthy and fibrotic tissue [49–51], which often go undetected by traditional automated scanners and software. Computer-assisted digital image analysis (DIA) offers a promising alternative [50–53], enabling quantitative and qualitative fibrosis evaluation by segmenting the area of interest and counting relevant pixels [49]. DIA precisely measures the diseased organ surface area while excluding irrelevant regions, although adoption is limited by high scanner and software costs and a lack of standardization [51]. A further obstacle is the subjective nature of histopathological evaluation; up to 84% of interpretations differ, requiring at least two specialists to reduce inconsistencies [52]. Artificial intelligence (AI) helps address this challenge by analysing digital images with greater precision and uniformity, reducing interpretive variability [52]. AI also assists pathologists in quantifying fibrosis and cirrhosis, essential for disease progression assessment, and accurately evaluates scarring [53]. In a global survey of 487 pathologists from 54 countries, 71% believed AI could improve their efficiency, though most still favour human authority in final decisions [48]. This reflects growing acceptance of AI's role, balanced by ethical considerations and the need for human oversight [50, 53]. Though AI and DIA can transform diagnostics by improving accuracy, efficiency, and objectivity, integration into clinical practice requires further in-

vestment in hardware, software, and standardization, ensuring accessibility and optimal outcomes [52, 53]. AI's potential extends beyond diagnosis to predicting disease progression and enabling personalized therapies, such as identifying cases most likely to progress to cancer for early intervention [53, 54].

Challenges

The growing scale and importance of AI in the health sector is evident from substantial financial commitments, such as the European Commission's investment of \$20 billion in 2020 [4]. The health sector has been identified as a priority area for AI development, with the potential to bring about groundbreaking changes ranging from enhanced diagnostic processes to optimized patient treatment [4, 55]. Indeed, AI is already yielding benefits in fields such as medical image analysis, pathological diagnostics, and therapy personalization. Nevertheless, despite these advancements, significant challenges remain before AI can be fully integrated into routine diagnostics [56]. One major hurdle is the limited availability of data, particularly in the context of rare diseases. This shortfall poses a serious barrier to the development and training of AI algorithms. In the diagnosis of rare diseases – such as certain types of cancer or genetic disorders – the number of accessible histopathological slides and other image data is often insufficient, impeding the creation of effective AI models [2, 57]. Because AI systems depend on large and diverse datasets to learn to identify patterns and accurately predict outcomes, a paucity of such data restricts the algorithms' effectiveness [57]. Another notable challenge lies in adapting the workflows of pathologists to incorporate new technologies. Implementing AI tools entails using costly scanners, sophisticated data management systems, and advanced software, which demands significant financial investments and modernization of medical facilities [2, 58]. Additionally, the introduction of AI requires adjustments in pathologists' daily routines, necessitating time, training, and adaptation to new diagnostic environments. Pathologists must also be convinced that the long-term advantages of AI – such as enhanced efficiency – outweigh potential risks, including misinterpretation of results or diminished control in decision-making processes. Their support is critical, as they play an essential role in integrating AI into everyday clinical practice [58, 59]. Furthermore, the growth of AI and digital technologies in medicine will facilitate ongoing digitization of diagnostic data, such as histopathological images, test results, and genetic information. While this transition enables easier data accessibility, analysis, and sharing among specialists, it also presents challenges related to network security and patient privacy. As highlighted, “due to this ubiquitous availability, network security and de-

identification of personal data have never been more important” [3, 59]. Consequently, introducing new regulations and security standards will be essential to safeguard patient data from unauthorized access and to comply with privacy laws such as the GDPR [59]. Although AI holds enormous promise for revolutionizing the healthcare sector, overcoming various technical and organizational obstacles is crucial before it can be widely adopted in clinical settings. These challenges include data access constraints, infrastructure modernization, workflow adjustments, and the education and persuasion of medical professionals. Yet, if these barriers are addressed, AI has the potential to greatly enhance diagnostic precision, improve treatment efficacy, and ultimately benefit patients worldwide [60, 61].

Conclusions

Artificial intelligence is playing an increasingly important role in pathology, revolutionizing diagnostics and supporting physicians in making accurate medical decisions. AI enables automatic analysis of microscopic images, identification of neoplastic lesions and tissue differentiation, which increases the precision of diagnoses and shortens the time to results. Examples of applications include diagnosing cancers such as breast, lung and prostate cancer, where AI algorithms often outperform traditional methods, detecting even small metastases that may be missed by the human eye. In studies such as CAMELYON16, AI algorithms such as LYNA outperformed pathologists in detecting breast cancer metastases, increasing diagnostic sensitivity and reducing slide review time. These results show that AI has the potential not only to support pathologists, but also to significantly improve diagnostic processes, minimize errors and enable a personalized approach to patient treatment. Although AI offers many benefits, its full implementation faces numerous challenges, such as the need to validate algorithms, modernize infrastructure, and convince clinicians to use new technologies. Nevertheless, the development of AI in pathology promises to improve the quality of medical care, reduce diagnostic errors, and implement appropriate therapies more quickly, ultimately benefiting patients worldwide.

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Conflict of interest

The authors declare no conflict of interest.

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